IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

United States of America
***ex rel.* John Doe,**

Plaintiff,

vs.

William Thomas Odom, II, M.D.

Defendant.

FILED UNDER SEAL

Pursuant to 31 U.S.C. § 3730(b)(2) & (3)

Jury Trial Demanded

3:20-cv-00803-CMC

Medicare pays physicians and entrusts them to conform to accepted standards of medical practice to help their patients. Defendant abused this trust and instead chose to pocket approximately $1 million by victimizing vulnerable patients with unnecessary injections that risk patient harm in many ways, including nerve damage, infection, reaction to medication, and broken needles.

COMPLAINT

1. *Qui tam* Plaintiff Relator "John Doe," M.D., through his attorneys, brings this Complaint on behalf of the United States and on his own behalf, pursuant to the federal False Claims Act, 31 U.S.C. § 3730 *et seq*. and alleges Dr. Odom submitted claims for reimbursement from the U.S. Government for medically unnecessary and unreasonable:

- anesthetic nerve injections,
- nerve transmission studies, and
- ultrasonic guidance imaging.

I. Jurisdiction, Venue, and Parties

2. This Court has jurisdiction under 31 U.S.C. § 3732 and 28 U.S.C. § 1345.

3. This Court has personal jurisdiction over Defendant because he transacts business and can be found in this district and committed acts within this district that violate 31 U.S.C. § 3729 and 31 U.S.C. § 3732(a).

4. Upon information and belief, no jurisdictional bars apply. 31 U.S.C. § 3730(e).

5. Venue is proper in this district under 31 U.S.C. § 3732(a) and 28 U.S.C. §1391(b) and (c) because Defendant resides and/or transacts business in this district and has committed acts within this district that violate 31 U.S.C. § 3729.

6. Relator has complied with all procedural requirements of 31 U.S.C. §3730(b)(2).

7. **Relator/ Qui Tam Plaintiff "John Doe"** is a medical doctor and Board Certified by the American Board of Surgery in General Surgery-Hand Surgery. Relevant to the allegations below, Dr. "Doe" uses anesthetic blocks with almost all surgeries and anesthetic injections are part of his daily practice.

8. While Relator Dr. "Doe" has significant evidence of the frauds alleged herein (the details of which follow), much of the documentary evidence necessary to prove the allegations is in the possession of Defendant and the United States. Based upon his knowledge, data, and personal experience, Relator has a reasoned factual basis to assert these allegations made upon information and belief.

9. **Defendant William Thomas Odom**, **M.D.** is enrolled in and provides services to beneficiaries under the Medicare Program, and submits claims for Medicare payments under NPI 1598717167.

10. The South Carolina Board of Medical Examiners shows that Dr. Odom has practiced medicine since 1992 under license 16893. Medical license records show Defendant practices medicine in Irmo in Lexington County, SC.

11. Relator's investigation has found Dr. Odom has no hospital privileges, that he does not participate in Medicaid, that he is Board certified in anesthesiology, but not Board certified in pain management.

II. The False Claims Act and Medicare

12. The Federal False Claims Act prohibits the submission of false or fraudulent claims and false statements so as to obtain or keep federal money. It provides, in pertinent part:

> (1) In general. — Subject to paragraph (2), any person who —
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . ., plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

13. Under the False Claims Act, a private person may sue in federal district court for him/herself and for the United States and may share in any recovery. 31 U.S.C. § 3730(b). That private person is a *relator*, and the action that the relator brings is called a *qui tam* action.

14. Under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted from $ 5,500 to $ 11,000 for violations occurring on or after September 29, 1999. For violations that occurred after November 1, 2015, Department of Justice (DOJ) announced increased penalties to between $10,781 and $21,562 per fraudulent claim.[1]

15. Medicare, enacted in 1965 under Title XVIII of the Social Security Act, is a third-party reimbursement program that underwrites medical expenses of the elderly and the disabled. 42 U.S.C.§§ 1395 *et seq*. Medicare reimbursements are paid from the federal Supplementary Medical Insurance Trust Fund.

16. Medicare Part B generally covers physician services, including medical and surgical treatment and outpatient treatment and diagnosis. Part B, 42 U.S.C. §§ 1395j *et seq*.; 42 U.S.C. §1395l (payment of benefits). The Medicare claims in this case arise under Medicare Part B.

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[1] https://www.federalregister.gov/documents/2017/02/03/2017-01306/civil-monetary-penalties-inflation-adjustment-for-2017

17. Physicians must enroll in the Medicare program to be eligible to receive payment for covered services provided to program beneficiaries. 42 C.F.R. § 424.505.

18. CMS requires that all claims for physician services be submitted on a form CMS-1500 (Health Insurance Claim Form) ("Form 1500") or its electronic equivalent. 42 C.F.R. 424.32 (Basic requirements for all claims).

19. At all times relevant to this action, Defendant submitted, or caused to be submitted, the electronic equivalent of Form 1500 to CMS. Form 1500 requires the submitting healthcare provider to include various fields of information prior to reimbursement, including: the date(s) of service; a code for the service(s) provided known as a "Current Procedural Terminology Code" or "CPT Code"); and the rendering healthcare provider's national identification number ("National Provider Identifier" or "NPI") and signature.

20. According to Form 1500's instructions, a provider's signature certifies "that services shown on [the Form 1500] were medically indicated and necessary for the health of the patient and were personally furnished by [the provider] or were furnished incident to [his/her] professional service by [his/her] employee under [his/her] immediate personal supervision."

21. Providers, such as Defendant, submit claims to Medicare by transmitting them to a private carrier or a Medicare Administrative Contractor ("MAC"), which processes the claims on behalf of HHS/CMS.

22. All healthcare providers that submit claims electronically to CMS or to CMS MACs, must certify in their application that they "will submit claims that are accurate, complete, and truthful," and must acknowledge that "all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other

information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." *See* Medicare Claims Processing Manual, § 30.2.A.

23. Medicare permits reimbursement only for medical treatments which are "reasonable and necessary for the diagnosis and treatment of illness or injury . . .." 42 U.S.C. § 1395y(a)(1)(A). *See also* 42 C.F.R. § 411.15(k)(1). The Secretary may issue National Coverage Determinations to define what services are considered reasonable and necessary, and if there is no applicable national coverage determination, a Medicare contractor may issue a "local coverage determination" stating whether an item or service is covered within that contractor's juridiction. *Id*. § 1395ff(f)(2)(B). Where there is no applicable national or local coverage determination, Medicare contractors "make individual claim determinations . . . based on the individual's particular factual situation." 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003).

24. Courts have looked for guidance to the CMS Medicare Program Integrity Manual and its elucidation of what is "reasonable and necessary." The Manual includes at § 13.3 (incorporating § 13.5.1's definition of reasonable and necessary for individual claim determinations), among these definitional requirements, that the service is:

- Safe and effective;
- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the patient's medical needs and condition;
- One that meets, but does not exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

25. Additionally, when considering medically "reasonable and necessary" CMS and courts looks to general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

- Scientific data or research studies published in peer-reviewed medical journals;
- Consensus of expert medical opinion (i.e., recognized authorities in the field); or
- Medical opinion derived from consultations with medical associations or other health care experts.

26. Healthcare providers who submit claims to the Medicaid Program must certify, in addition to medical necessity and reasonableness, that all statements in the claim are true, accurate, and complete to the best of the provider's knowledge; that no material fact has been omitted; that the provider is bound by all rules, regulations, policies, standards, fee codes and procedures.

27. Medicare further requires that services be provided "economically" and that they are supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing quality improvement organization in the exercise of its duties and responsibilities. 42 U.S.C. § 1320c-5.). Under Medicare rules and policies, healthcare providers must contemporaneously create and maintain accurate medical records to support the providers' claims for reimbursement. *See e.g.*, CMS MLN Matters Number: SE1022 ("Providers/suppliers should maintain a medical record for each Medicare beneficiary that is their patient. Remember that medical records must be accurately written, promptly completed, accessible, properly filed and retained").

28. When submitting a claim for reimbursement, the claimant must provide documentation that supports the claim. Appropriate documentation typically involves correctly coding certain services to enable the Government to reimburse the healthcare provider at the proper rate.

29. "Upcoding" is an act of committing fraud by knowingly and intentionally submitting a claim under an inappropriate diagnostic or procedural code to obtain a higher rate of reimbursement. Upcoding also occurs by changing the procedure code to a code that pays a higher rate of reimbursement.

30. Upcoding can harm patients medically and financially. Fabricated medical histories in patients' charts and medical records can forever skew diagnoses and treatment. This may cause a patient to undergo additional diagnostic exams or even cause a subsequent healthcare provider to perform a procedure that might be unnecessary were the patient viewed as lower risk. In addition, a patient may be declined or charged more for long-term care or life insurance due to these false diagnoses.

III. False Claims for Unnecessary Anesthetic Injections

A. Procedure overview and risks of harm

31. CPT 64450 is "injection of anesthetic agent, other peripheral nerve or branch." LCD 64450. An LCD describes the procedure:

> Nerve blocks cause the temporary interruption of conduction of impulses in PERIPHERAL nerves or nerve trunks by the injection of local anesthetic solutions.
>
> The use of nerve blocks or injections for the treatment of multiple neuropathies or PERIPHERAL neuropathies caused by underlying systemic diseases is not considered medically necessary. Medical management using systemic medications is clinically indicated for the treatment of these conditions.
>
> …
>
> *Utilization Guidelines*: Treatment protocols utilizing multiple injections per day on multiple days per week for the treatment of multiple neuropathies or PERIPHERAL neuropathies caused by underlying systemic diseases are not considered medically necessary.

LCD 35222. LCD 35222, covered South Carolina and 47 other states under Part A, but not South Carolina Part B.[2]

32. Another LCD, L37642, provides in part: "Nerve blocks, injections of local anesthetic solutions, cause the temporary interruption of conduction of impulses in peripheral nerves or nerve trunks."[3]

33. Unnecessarily inserting needles to inject medications risks patient harm. These risks include:

- Temporary and permanent nerve damage from hitting a nerve. For example, sciatic nerve damage can lead to lower limb paralysis.
- Puncture of a blood vessel (intravascular injection). Consequences can include: tinnitus, blurred vision, dizziness, tongue parathesias, and circumoral numbness or cardiac arrest.
- Infections around the injection location. Bacterial infection may cause cellulitis (subcutaneous fatty tissue inflammation) or abscesses.
- Adverse reactions to injected medications, such as possible allergic reactions. Steroidal injections can risk harm by causing tendon rupture, skin discoloration, or allergic reactions.

34. Injected medications may also have side effects and repeat injections increase the likelihood of side effects. This is even more of a risk for elderly patients on blood-thinning medications, with active infections, or with poorly controlled diabetes or heart disease. Risks from anesthetic's toxic effects can be local or systemic.

- Local toxic effects include prolonged anesthesia and paresthesia (an abnormal tingling, pricking, chilling, burning, or numb sensation) which may become irreversible.

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[2] https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35222&ver=16&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=Texas&CptHcpcsCode=64450&bc=gAAAACAAAAAA&.

[3] Nerve Blocks and Electrostimulation for Peripheral Neuropathy (L37642). https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37642

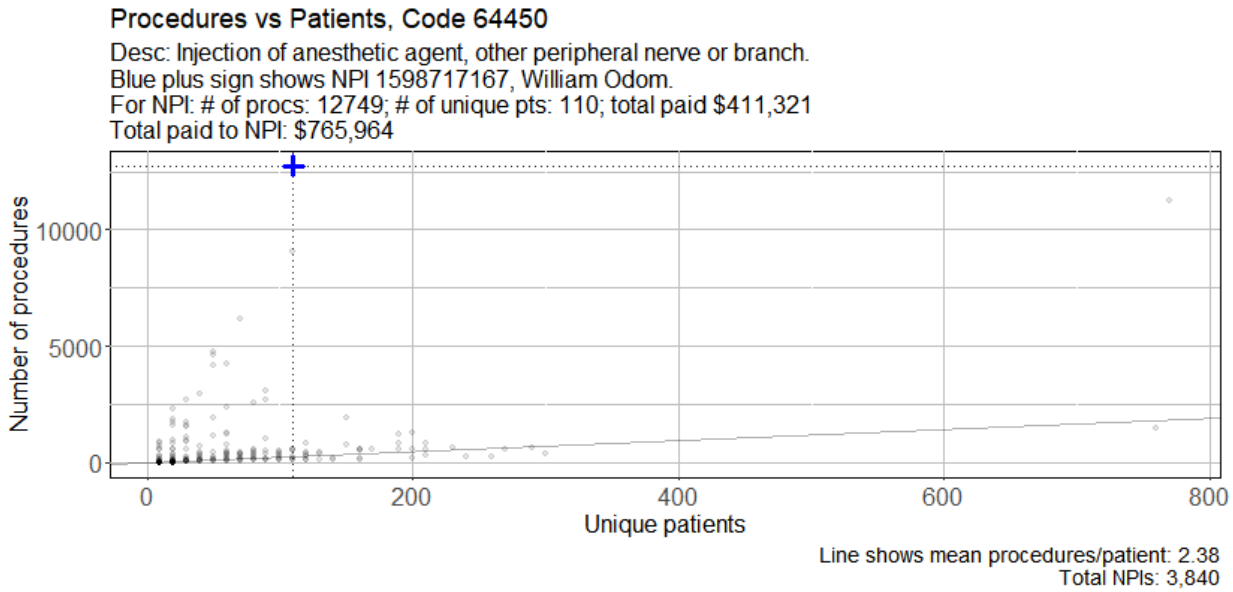
- Systemic toxicity often involves the central nervous system or the cardiovascular system and may cause death or permanent brain dysfunction. Anesthetic agents can be toxic if administered inappropriately and, occasionally, even when properly administered.

B. Defendant's repeat claims

35. Medicare paid Defendant the following amounts for CPT 64450 "Injection of anesthetic agent, other peripheral nerve or branch." In 2017, Dr. Odom claimed Code 64450 *more often than any doctor submitting claims under Medicare Part B.*

Year	CPT 64450	64450 Patients	Claims	Claims / Pt
2015	$ 0	0		
2016	476,715	94	14,541	155
2017	411,321	110	12,749	116

36. Although Defendant averaged 155 and 116 claims *per patient*, for some patients the number was lower and for others the number was higher. In contrast, the nationwide mean is 2.3 claims per patient.



C. Claims driven by financial considerations

37. Relator's experience and investigation show that patients who seek assistance with pain know their symptoms, but they do not specifically seek treatment by CPT 64450 "injection of anesthetic agent, other peripheral nerve or branch."

38. With respect to the CPT 64450's customary practices and standards of care in South Carolina, Relator's investigation revealed there was no "cluster" of symptoms or diagnoses that would indicate Defendant Odom's volume of repeat procedures are medically reasonable or necessary.

39. Relator's investigation has determined that Defendant Odom's reputation in the professional community would not have brought about referrals of patients with special needs requiring such unusual treatment.

40. If Defendant Odom actually performed the number of procedures per patient that he claimed then he unnecessarily risked patient harm. The CPT code 64450 claims Dr. Odom submitted to Medicare reflect a pattern in which patients risk excessive frequency for unnecessary and potentially risky injections.

41. For these reasons, Relator alleges that many or most the claims submitted by Dr. Odom for CPT 64450 are false.

IV. False Claims for Unnecessary 95909 Nerve Transmission Studies

42. The American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) defines electrodiagnostic medicine and needle electromyography (EMG):

> The electrodiagnostic medicine (EDX) evaluation serves to evaluate patients with disorders of the peripheral and/or central nervous system, and other neuromuscular (NM) disorders.

43. The LCD governing South Carolina Part B provided guidance on the number of electrodiagnostic (ED) studies by incorporating by reference AANEM's "Model Policy for Needle EMG and NCS. Nerve Conduction Studies and Electromyography (L35048).[4]

44. AANEM's position on nerve conduction both describes these diagnostic tests and recommends the number of tests required ("the minimum necessary") for a diagnosis.

> *CPT Codes 95907-95913: Nerve Conduction Studies Overview*
> 1. NCSs (CPT codes 95907-95913) are performed to assess the integrity and diagnose diseases of the peripheral nervous system. Specifically, they assess the speed (conduction velocity, and/or latency), size (amplitude), and shape of the response. Pathological findings include conduction slowing, conduction block, no response, and/or low amplitude response. …
> 6. *The number of nerves tested should be the minimum necessary to address the clinical issue.* In almost all studies, this will appropriately include evaluation of 1 or more nerves that have normal test results.

AANEM Position Statement [emphasis supplied]. [5]

45. These diagnostics are generally safe, but they do pose some risks.

> These studies are generally well tolerated and rarely thought to be associated with any significant side effects. *However, needle electromyography is an invasive procedure* and under certain situations has the potential to be associated with iatrogenic complications, including *bleeding, infection, nerve injury, pneumothorax, and other local trauma.* Similar complications are possible if needles are used for either stimulating or recording. In addition, like all other electrical devices and monitoring equipment connected to patients, electrodiagnostic testing carries the risk of stray leakage currents that under certain circumstances *can result in electrical injury*, especially in patients in the intensive care setting. Similarly, certain precautions are required during nerve conduction studies (NCS) in patients with pacemakers and other similar cardiac devices.

Iatrogenic complications and risks of nerve conduction studies and needle electromyography. https://www.ncbi.nlm.nih.gov/pubmed/12707972 [emphasis supplied]

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[4] https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35048

[5] https://www.aanem.org/getmedia/c50c666e-c04b-46bc-9156-6f1f986db5e1/PositionStatement-Overview_of_EDX_Med.pdf.aspx

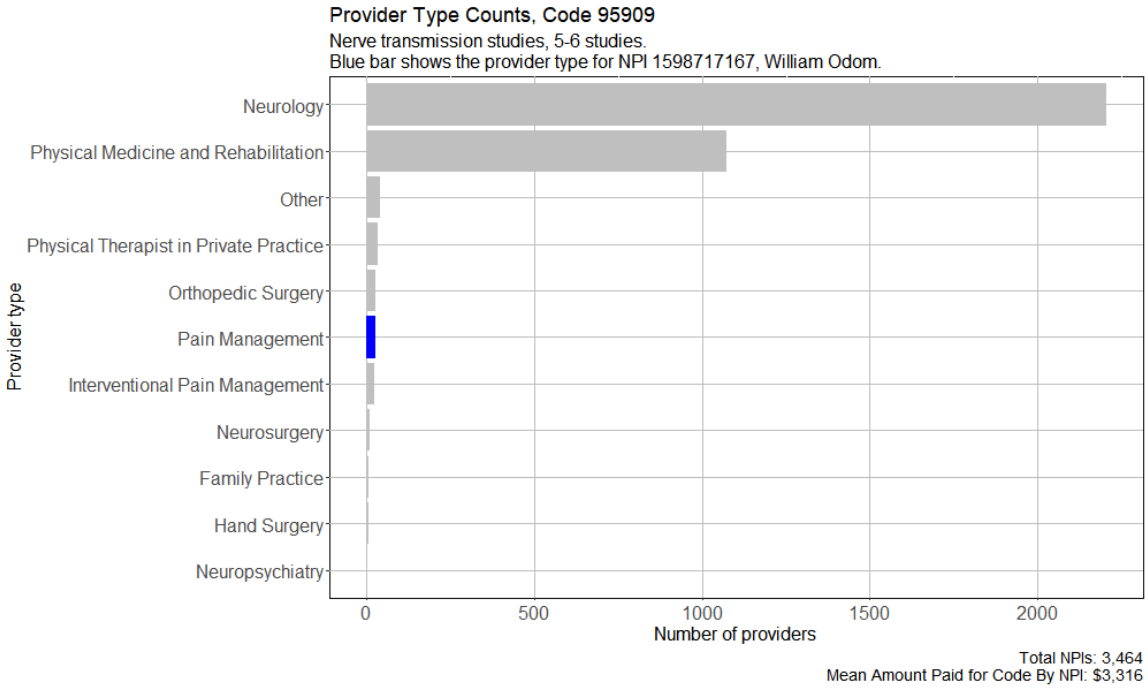
46. Medicare reimbursement is based on the number of studies, and medical providers across the country find it medically reasonable and necessary to perform more studies on some patients and fewer studies on others.

47. The table below shows claims under Medicare Part B in 2016.

Code, # of studies	National	
95907, 1-2 studies	4,692	1%
95908, 3-4 studies	50,942	8%
95909, 5-6 studies	119,556	20%
95910, 7-8 studies	141,980	23%
95911, 9-10 studies	149,376	25%
95912, 11-12 studies	64,754	11%
95913, 13 or more studies	74,674	12%
Total	605,974	100%

48. The procedure is most frequently claimed by neurologists, and only rarely claimed by pain management physicians.

49. The table below shows only code 95909 claims sorted by specialty, but it is representative of all codes 95908 – 95913. However, there is nothing inherently fraudulent about a pain management physician, such as Defendant, claiming a nerve transmission study.



50. In 2016, and only in 2016, Medicare paid Defendant for 624 claims for CPT 95909 *5-6 nerve transmission studies,* for 105 patients.[6] These claims indicated that none of those patients required fewer than five or more than six studies,

Year	srvc cnt	patients	amt paid	National Rank
2014	0	0	0	n/a
2015	0	0	0	n/a
2016	624	105	$ 67,211	# 2
2017	0	0	0	n/a

But CMS shows Defendant submitted no claims in 2014-2017 for:

95907	Nerve transmission studies, 1-2 studies
95908	Nerve transmission studies, 3-4 studies
95910	Nerve transmission studies, 7-8 studies
95911	Nerve transmission studies, 9-10 studies
95912	Nerve transmission studies, 11-12 studies
95913	Nerve transmission studies, 13 or more studies

51. On average, Defendant claimed code 95909 *six* times per patient. Based on Relator's knowledge and experience, Defendant's repitions indicate the initial service was performed incorrectly (and thus a false claim), or that the first or the following services were not medically necessary.

52. Consistent with Relator's medical opinion, nearly all other physicians who submitted claims for this procedure claimed it *only once* per patient.[7]

53. Based on Relator's medical experience and his investigation, the claims also seem implausible because of their impact on Defendant's practice. The claims, if true, would require a significant portion of Defendant's time performing the studies in 2016. Based on AANEM Position Statement estimates that the evaluations take between 30 minutes and up to two hours to perform, Relator calculated, based

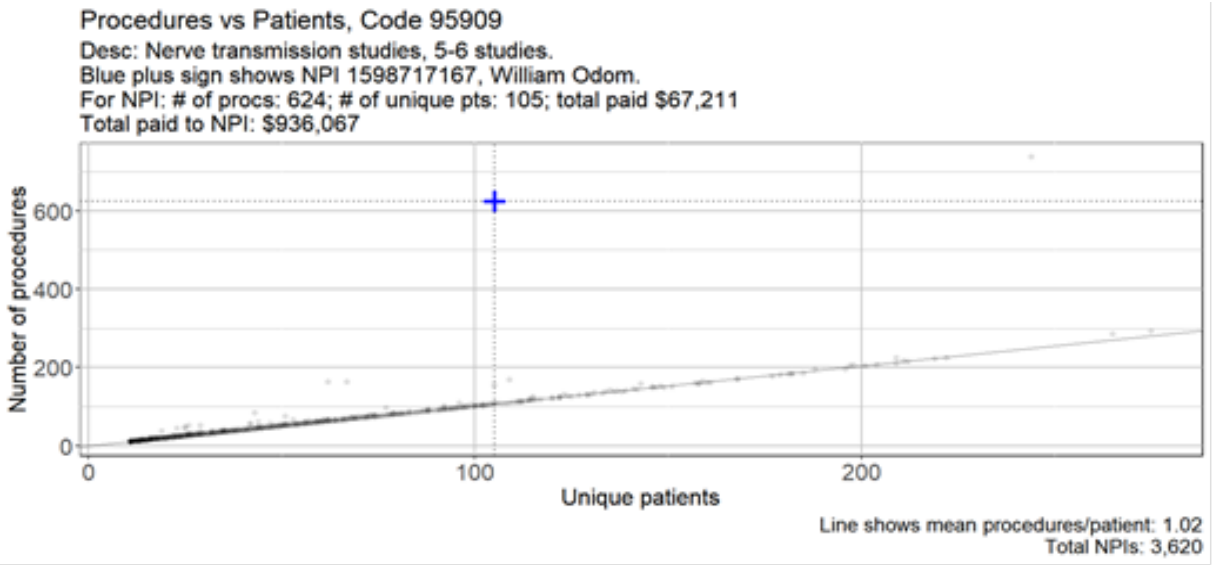
[6] CMS suppresses data when there are 10 or fewer patients.

[7] Based on 2017 CMS data, Relator identified 3,464 NPIs who claimed the procedures, and calculated they claimed 1.02 mean procedures per patient.

on a conservative 45 minutes per study, that *624 studies would require 468 hours*, about one quarter of a typical work year.[8]

54. Defendant's practices differ from other providers' accepted standards of medical practice

- because he files or causes claims to be filed only for code 95909 (5-6 studies), and files no claims for codes 95901, 95908, 95910, 95910, and 95913 (fewer than five or more than six studies), and
- because he repeats the studies, and averages six 95909 (5-6 studies) claims per patient.



55. In Relator's experience and professional opinion, it is both implausible and beyond the standards of care that 105 patients arrived in Defendant's office, all of whom required 5 to 6 studies, none more and none less, and that it was necessary to have patients return again and again to repeat the diagnostic, and that this was "reasonable and necessary for the diagnosis" and that such studies were made in accordance with accepted standards of medical practice for the treatment of the patient's

[8] http://www.radiologybillingcoding.com/2017/02/cpt-95886-95911-95913-95910-95885-nerve.html AANEM Position Statement "The AANEM believes that nonphysician providers, including physical therapists, chiropractors, physician assistants, and others, lack the appropriate training and knowledge to perform and interpret EMG studies and interpret NCSs."

conditions, and not simply to increase Defendant's profits. *See* 42 U.S.C. § 1395y(a)(1)(A). *See also* 42 C.F.R. § 411.15(k)(1).

V. False Claims for Ultrasonic Guidance Imaging Supervision

56. Dr. Odom submitted claims for CPT 76492, "Ultrasonic guidance imaging supervision and interpretation for insertion of needle."

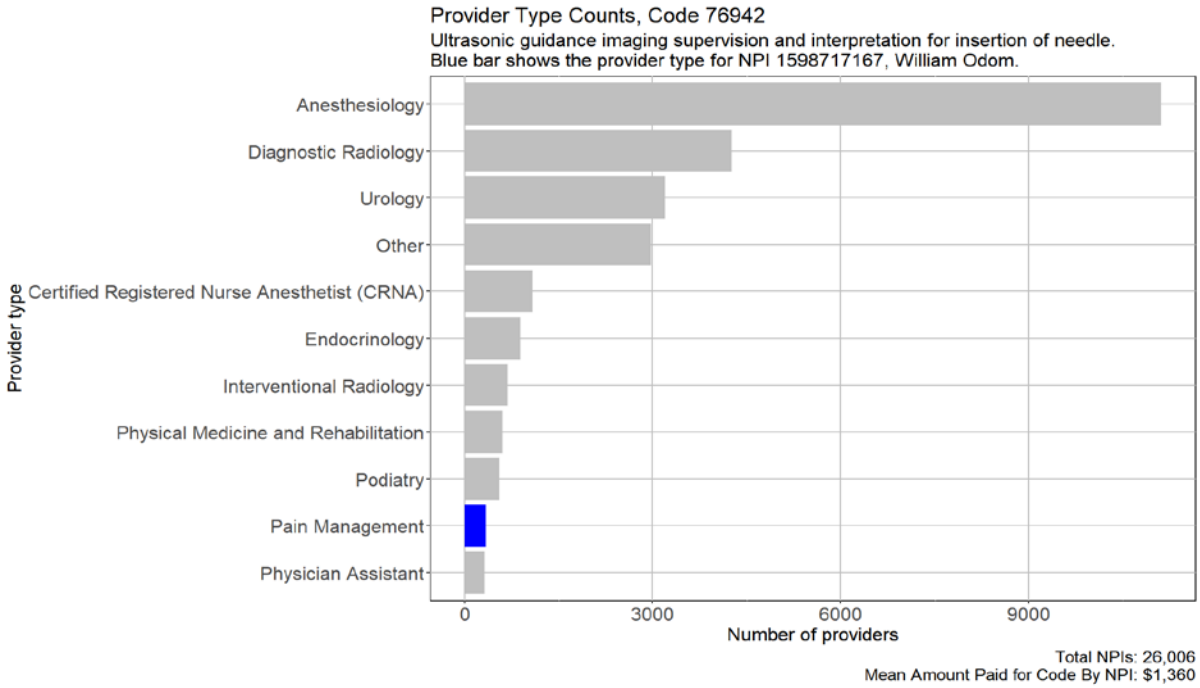
year	srvc	pts.	clms / pt	paid
2014	1,377	279	4.9	$ 70,659
2015	171	99	1.7	7,525
2016	79	32	2.5	3,378
2017	55	27	2.0	2,461

57. Ultrasound guidance *imaging* helps place needles deep within a patient at a site that is not visible. For example, ultrasonic guidance would be necessary in a hospital to remove fluid from a lung or a deep cyst that cannot be located visually. However, if there is fluid in a knee, a physician does not require ultrasonic guidance to find a knee cap or the space beneath it.

58. There exist few indications for using ultrasound guidance.[9] This is especially so for Defendant who would generally not be referred patients with problems deep within the body.

59. Because ultrasonic guidance is required to help place needles deep in a body, it is typically claimed by those who deal with issues deep in patients bodies, such as anesthesiologists, diagnostic radiologists, and urologists. Although there is nothing inherently fraudulent about a pain management physician claiming code 76942, it is unusual.

[9] CMS National Correct Coding Initiative, Ch. 9 final10312018. https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html



The use of ultrasound guidance in conjunction with non-covered CPT 64450 injections (or any unnecessary injection) would also be considered not medically necessary. *See e.g.* LCD L35333 (unnecessary nerve blocks cannot justify unnecessary guidance).[10]

60. Because so many of Defendant's CPT 64450 injections are not medically necessary, Relator believes many or most of the claims Defendant submitted for CPT 76942 claims are also false.

VI. Counts I – II

A. Count I: Violations of 31 U.S.C. § 3729(a)(1)(A)

Plaintiff repeats and realleges the preceding paragraphs as if fully set forth herein.

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[10] https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35222&ver=13&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCD&PolicyType=Final&s=51&KeyWord=peripheral&KeyWordLookUp=Doc&KeyWordSearchType=Exact&CptHcpcsCode=64450&kq=true&bc=IAAAACAAAAAA&

61. Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval to Government Health Care Programs, all in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

62. The United States paid said claims and has sustained damages because of these acts by the Defendant.

B. Count II: Violations of 31 U.S.C. § 3729(a)(1)(B)

Plaintiff repeats and realleges the preceding paragraphs as if fully set forth herein.

63. Defendant knowingly made, used or caused to be made, or used false records or statements material to a false or fraudulent claim, all in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

64. The United States paid said claims and has sustained damages because of these acts by Defendant.

PRAYER

WHEREFORE, *Qui Tam* Plaintiff Relator, for the United States and for himself, prays that judgment be entered against Defendant as follows:

A. For each count, the amount of damages, trebled as required by law, and civil penalties up to the maximum permitted by law,

B. For the maximum *qui tam* percentage share allowed by law,

C. For attorney's fees, costs and reasonable expenses, and

D. For any and all other relief to which Plaintiffs may be entitled.

Plaintiff requests trial by jury.

(Signature Block on Following Page)

s/John C. Moylan, III

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